6 Resource Requirements

6.4 Equipment (Instruments, reagents, consumables, reference material)

6.4.1 The TBI-FSD is furnished with, or has access to, all equipment needed for the correct performance of forensic examinations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). All equipment having an effect on the accuracy or validity of forensic examination/calibration results will be evaluated as fit for use, properly maintained and calibrated.

6.4.2 When there is a need to use equipment outside the permanent control of the TBI-FSD, personnel will ensure the requirements of ANAB are met.

6.4.3 Laboratory units will have procedures for appropriate storage, transportation, use, and planned maintenance of all equipment to ensure proper functioning and in order to prevent contamination and deterioration.

6.4.3.1 Reagents prepared in the TBI Laboratory will be labeled with, at a minimum, the identity of the reagent, the date of preparation or lot number. Records will identify who made the reagent, the date of preparation or lot number, who tested it, and whether it worked as expected. Reliability testing must occur before use if there is a limited amount of evidence sample. Reliability testing may run concurrent with testing if sample size of evidence allows for possible retesting. Unit SOPs may establish additional requirements regarding the preparation of reagents. Unit SOPs will have procedures for routinely checking the reliability of reagents.

6.4.3.2 Reference collections of data or materials which are maintained for identification, comparison or interpretation purposes shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest. These references may include mass spectra, headlamp lenses, drug samples, bullets, cartridges, DNA profiles, and frequency databases.

Breath alcohol calibration reference materials, either obtained from an external source or manufactured by the laboratory, shall be labeled with, at a minimum, the:

- identity of the reference material; and
- date of preparation or lot number.

Records shall be maintained to include:

- applicable calibration certificates;
- concentration of specified contents;
- source or preparer of the material; and

- data arising from intermediate checks carried out to maintain confidence in the calibration status of the reference material.

6.4.4 Equipment (instruments, reagents, reference material and consumables) used to perform laboratory activities must meet the requirements of the appropriate Unit SOPs. Equipment shall be determined fit for use. If equipment is removed from service, fitness for use shall be established prior to placing back into service.

6.4.5 Specific laboratory equipment shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide valid results per appropriate Unit SOPs.

6.4.6 The TBI-FSD requires any instrumentation having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling, will be calibrated or performance checked prior to being put into service for forensic examinations.

If the calibration is a significant component of the measurement of uncertainty, traceability to the International System of Units (SI units) must be establish.

Internal calibrations of instrumentation will establish traceability by means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement.

When necessary, calibrations will be performed by competent external calibration services demonstrating measurement capability and traceability. The calibration certificates issued by these entities will contain the calibration results, including the measurement of uncertainty, and/or a statement of compliance with an identified metrological specification.

6.4.7 Units with laboratory equipment requiring routine calibration or performance checks will have established procedures. The procedures will address specific requirements of the laboratory activity being carried out. The procedures shall include:

- A list of all equipment requiring calibration/performance checks;
- Specifications for the calibration provider;
- Specified requirements for calibration/performance checks;
- The interval between calibrations/performance checks. Intervals will generally not be longer than the manufacturer's recommendations.

If an instrument can be affected by a power interruption, unit personnel will check the calibration/performance after a shutdown.

Instrument calibration/performance will be checked following service or other substantial maintenance.

Calibration/performance check procedures shall be evaluated as necessary by the appropriate technical leader. Any extension in the interval of calibration/performance check shall be based on documented empirical data and an evaluation of risk.

6.4.8 TBI-FSD instrumentation requiring calibration/performance check will be labeled or otherwise identified to indicate the calibration/performance check status, when practicable.

6.4.9 Any instrumentation that has been subjected to overloading or mishandling, is malfunctioning, outside specified limits, or giving suspect result will be taken out of service. Only when it is shown by calibration/performance check to operate correctly will the instrument be returned to service. Units will determine the effect of the malfunction, if any, on test results and implement “Control of Nonconforming Testing”. Equipment that is out of service shall be labeled accordingly until the necessary repairs have been completed. The Crime Laboratory Regional Supervisor will be notified if scientific instruments, equipment, or balances require outside maintenance support.

6.4.10 The need for intermediate checks to maintain confidence in the performance status of instrumentation, reference, primary, or working standards as well as reference materials will be established in unit SOPs. When intermediate checks are determined to be necessary, they will be done according to unit SOPs. Unit SOPs shall define the frequency of intermediate checks of the performance status. Any change to the frequency of intermediate checks shall be based on empirical data supporting the change and an evaluation of the risk associated with the change.

6.4.11 Where instrument calibrations produce a set of correction factors, measures will be taken to ensure the copies (e.g. in computer software) are correctly updated.

6.4.12 Each discipline will ensure instrumentation used for forensic examinations and calibration activities, including both hardware and software, are safeguarded from adjustments which would invalidate the test results.

6.4.13 The TBI-FSD will maintain procedures for and records of all instrumentation and, if applicable, it’s associated software used for forensic examinations and calibration activities. The records will include the following:

- The unique identity of the instrument and its software;
- The manufacturer’s name, type identification, and serial number;
- Verification the equipment complies with the specification;
- The current location, where appropriate;
- The manufacturer’s instructions, if available, or reference to their location;
- Dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of the next calibration;
- The maintenance plan, where appropriate, and maintenance carried out to date;

- Records for maintenance performed by an outside vendor will be maintained and may include the vendor's invoice/purchase order documenting the dates the maintenance was performed;
- Any damage, malfunction, modification, or repair to the equipment;
- Service records or logs. The records should include at a minimum, the date, individual's initials, any limitations, adjustments and/or repairs made.